CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020916

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-916

JUN 29 1998

Astra Merck
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Horowitz :

Please refer to your new drug application dated September 30, 1997, received September 30, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRILOSEC (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated November 7 and December 5, 1997, February 4, March 9, April 3, 9, 22, May 21, June 4, 16, 17, 25 and 29, 1998. The User Fee goal date for this application is September 30, 1998.

This new drug application provides for the concomitant use of PRILOSEC Delayed-Release Capsules, amoxicillin and clarithromycin for the eradication of *H. pylori* in patients with duodenal ulcer disease.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated June 29, 1998. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on June 29, 1998. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-916. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you

propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Robin Anderson, Project Manager, at (301) 827-2127.

Sincerely yours,

/S/

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogens and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDA 20-916
HFD-590/Div. files
HFD-590/CSO/R.Anderson
HFD-590/MO/R. Hopkins
HFD-002/ORM (with labeling)
HFD-104/Office Director
HFD-101/L.Carter
HFD-830/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-95/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFI-20/Press Office (with labeling)
HFD-180/CSO/M. Walsh

APPEARS THIS WAY
ON ORIGINAL

Drafted by: RA/June 19, 1998
Initialed by:
final:

APPROVAL (AP)

APPEARS THIS WAY
ON ORIGINAL